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IN THE
Supreme Court of the United States
OCTOBER TERM, 1991

GENETICS INSTITUTE, INC.,
and CHUGAI PHARMACEUTICAL CO., INC.,
Petitioners,

v.

AMGEN, INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF AMICUS CURIAE OF THE TAXPAYERS ASSETS PROJECT OF THE CENTER FOR STUDY OF RESPONSIVE LAW IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE* *

The Taxpayer Assets Project was established in 1988 by Ralph Nader and the Center for Study of Responsive Law to investigate a wide range of issues related to the responsible management of federal assets. Broadly speaking, the Project is interested in the nature and fairness of the bargain the government strikes when transferring

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* Consent of all parties has been granted to file this brief of Amicus Curiae in support of petitioners. Letters of Consent have been filed with the Clerk of the Court.

public assets to the private sector. The Project is particularly interested in the social cost of intellectual property and high technology, especially pharmaceuticals, energy, and natural resources. Project personnel have testified before Congressional Committees on those issues.

SUMMARY OF ARGUMENT

Although a patent appears to be a private right, that private right is only "secondary," as this Court has stated, to the public bargain of which it is but a part. The focus must always be whether the public has received full information about the nature of the invention so that future inventors can use and improve it. The decision below reflects a failure to recognize the patent's monopoly nature and as a result abandons the "best mode" rule forbidding the inventor from concealing the best way of replicating the invention. By turning the subjective test of "best mode" into an objective one, the decision below sacrifices the public interest, because it allows an inventor to conceal the invention's secrets so long as the inventor can convincingly argue that later experimenters might, through experimentation, luckily rediscover something close to them. Such a rule impermissibly abandons the public interest as well as established law and threatens to fatally deprive our patent system of its public value.

ARGUMENT

I. THE PUBLIC INTEREST IS THE PRIMARY FOCUS OF THE PATENT SYSTEM

The ownership of a patent monopoly over a life-saving pharmaceutical like the one in dispute here is no doubt critically important to the present litigants, but a very different, and overarching, principle is central to this case and profoundly important to this *amicus*, arising from an interest that will not necessarily otherwise be raised. It is the principle that the patent privilege is not given away

nor even traded cheaply but is policed and guarded by doctrines requiring that the applicant reveal all he knows in exchange for the public grant of private monopoly rights. In this case, the successful attempt to prevent others from acquiring the living cells at the heart of the invention should be fatal to the patent. An inventor's failure to deposit those cells is a clear violation of the patent bargain.

This Court has recognized that the focus of the patent system is not the admittedly important private right which it incidentally grants but, to the contrary, is the public benefits conferred. This Court has repeatedly observed that the reward to inventors is "secondary" to the public interest.[1] It is that public interest which should be the focus of all patent disputes. The full, fair, and replicable disclosure of the inventor's secret "is necessary in order to give the public, after the privilege shall expire, the advantage for which the privilege is allowed, and is the foundation of the power to issue the patent." [2, 3]

While it is natural that the idea of a patent—a legal monopoly—immediately evokes the notion of the private right bestowed upon the inventor, in truth our patent laws are premised on the notion that even more importantly than the inventor, the public gains something of value. The decision below, by addressing primarily, perhaps solely, the rights of the patentee and ignoring the public interest in receiving the full patent bargain, has dangerously distorted the nature of patent law. By allowing the patentee to withhold the secrets of the invention, the Federal Circuit has sacrificed that public interest.

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[1] *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942).

[2] *Grant v. Raymond*, 31 U.S. (6 Pet.), 247 (1832).

[3] "This fundamental principle—that legal protection is premised on an adequate disclosure of the invention—is built deep into the history of patent law." Merges and Nelson, "On The Complex Economics Of Patent Scope," 90 Colum. L. Rev. 839, 844-845 (1990).

Indeed, the very nature of our modern patent system reflects a rejection of its ancient origins whereby royal monopolies were bestowed selfishly, arbitrarily, and solely on the basis of the importance to the monarch of who was to receive it. From as early as the fourteenth century, the English crown shamelessly and blatantly awarded patent monopolies to its favored subjects. It is unsurprising, therefore, that the very first English patent statute, the Statute of Monopolies of 1623,[4] did not authorize the granting of patents so much as severely limit those abusive royal practices.[5] While the roots of our patent system may be found in those royal grants, its present shape represents an express rejection of those blatantly protectionist historical sources.

Though they highlight Enlightenment principles promoting the dissemination of knowledge, our patent laws also incorporate more ancient principles of fair and equitable exchange.[6] Under them, one seeking to exchange valuable rights must be open and fair with those with whom he seeks to bargain. That principle of fair exchange seems misunderstood or forgotten in the decision below. The opportunity, newly provided by that decision, to gain patent rights and yet maintain the secrecy of the invention is too dangerous to co-exist with a fair and open patent system. Unaddressed, that new doctrine will cause a slow but real erosion of the patent system. Not

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[4] 21 Jac., ch. 3.

[5] Armstrong, "From The Fetishism Of Commoditics To The Regulated Market: The Rise And Decline Of Property," 82 Nw. U.L. Rev. 79, 84-86 (1987). Burch, Note, "Ethical Considerations in the Patenting of Medical Processes," 65 Tex. L. Rev. 1139 (1987).

[6] Aristotle, Nichomachean Ethics 125 (M. Ostwald trans. 1962); Barnett, "A Consent Theory Of Contract," 86 Colum. L. Rev. 269, 283-284, 289-294 (1986); Rose, "Crystals and Mud in Property Law," 40 Stan. L. Rev. 577, 594-598 (1988).

only the public but private interests will lose, for those attempting to improve on the instant discovery cannot do so. Without access to the actual cell line, they cannot ever be sure of reproducing the invention. Our patent laws are expressly designed to achieve the opposite result.

II. THE PUBLIC INTEREST DEMANDS SPECIAL ATTENTION IN PATENT MATTERS BECAUSE OF THEIR SECRET, NONADVERSARIAL, *EX PARTE*, NATURE

Certainly inventions and technological progress can be made without a patent system. Even without the patent disclosures of inventors' "best modes",[7] discoveries though fewer, would still occur. Indeed, major historical discoveries and technical advances were accomplished before anything like our modern patent system ever existed. The discovery of fire and the invention of the wheel are pre-historical examples, while the printing press and square-rigged sailing mark later, pre-patent, advances. Without the full disclosure our patent system provides, however, we would all have far less access to advanced information, and invention would slow. Our modern patent system is premised upon the belief that an advanced technologically complex society will best progress through two cyclically related means: first, if access to necessary information is open, then new discoveries will increase; second, those discoveries can be multiplied further if inventors are given the incentive of a limited monopoly over the exploitation of certain breakthrough discoveries—"inventions" (statutorily defined as only those discoveries that are "new," "novel," and "nonobvious"[8])—the disclosure of which then serves to increase the first. For the cycle to work, all that is asked of the inventor is full and complete disclosure of the discovery.

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[7] 35 U.S.C. § 112.

[8] 35 U.S.C. §§ 101, 102, 103.

Indeed, it is of profound importance to our patent laws that in order to encourage inventors to file patent applications, the inventor is assured complete secrecy over the invention until and unless the patent is granted.[9] If a patent is denied, the secrecy continues and the inventor may revert to trade secrecy to try to prevent others from competing. Thus, the requirement of full disclosure of the "best mode" of practicing the invention is not an arcane statutory requirement, but reflects the most equitable aspirations of the patent system—that the public, in return for the patent monopoly, asks only that the applicant, protected by the fact of application secrecy—speak with the fullest candor when revealing his invention.

In fact, closely related to the "best mode" requirement, there is also a patent law doctrine called the "duty of candor," which requires that an applicant reveal, in addition to the invention itself, other information which might cast some doubt upon the legitimacy of the applicant's application.[10] Arising out of the secrecy of the patent system, the duty of candor recognizes the hazards of such an *ex parte* legal proceeding, in which there is no adversary to fully illuminate the process. In an attempt to fashion a quasi-adversary process, the duty of candor therefore requires the applicant to offer some of the kind of information normally supplied by an adversary. The "best mode" requirement obviously relies similarly upon the candor of an applicant.

The Federal Circuit's mistake cannot be fully appreciated without understanding how the Patent and Trade-

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[9] "Applications for patents shall be kept in confidence by the Patent and Trademark Office and no information concerning the same given without authority of the applicant or owner unless necessary to carry out the provisions of any Act of Congress or in such special circumstances as may be determined by the Commissioner." 35 U.S.C. § 122.

[10] *Hoffman-La Roche Inc. v. Lemmon Company*, 906 F.2d 684 (Fed. Cir. 1990); 37 C.F.R. § 1.56.

mark Office processes patent applications. Its procedures must, necessarily, be secret.[11] Except when an interference with another pending patent application is declared,[12] the processing of the application—its "prosecution"—is an entirely *ex parte* procedure.[13] As a result, from the application's filing until a patent is actually issued, cloaked, importantly, in a presumption of validity, the "prosecution" of the application—its processing within the Patent and Trademark Office—by the inventor is a serious misnomer, since the *ex parte* process mandated by secrecy bars the presence of any truly adverse parties. Relying upon the observance of such rules as Congress might mandate—such as the "best mode" requirement—the overworked and understaffed PTO is the sole guardian of the public interest.[14] That the Federal Circuit, in its decision below, saw fit to jettison the "best mode", relying upon an optimism over the presumed good luck of future investigators, is a serious abdication of the public interest.

Thus, a modern patent system like ours involves a significant risk, for the public receives its share of the bargain only when the applicant—unopposed and operating within the abnormally generous confines of a non-adversarial, secret, *ex parte* statutory system—plays by the rules and provides full and fair disclosure. By granting a patent, the public gives up the freely competitive economic marketplace upon which it normally relies, and establishes in its place a full monopoly, limited only by

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[11] 35 U.S.C. § 122, n.9.

[12] 35 U.S.C. § 135.

[13] 35 U.S.C. §§ 114, 122, 131, 132, 134.

[14] *Kahn v. Dynamics Corp. Of America*, 508 F.2d 939 (2d Cir. 1975); *Lyle/Carlstrom Associates, Inc. v. Manhattan Store Interiors, Inc.*, 635 F. Supp. 1371 (E.D.N.Y. 1986); Note, "An Economic Analysis of Royalty Terms in Patent Licenses," 67 Minn. L. Rev. 1198, 1202, 1227 n.127 (1983); Derra, "Patents Bury Biotech," *Research & Development*, Vol. 32; No. 2; Pg. 22 (December, 1990).

its seventeen-year term. Such a system demands rigorous policing and a watchful judicial eye. The decision below, however, has "given away the store", for it admits that the applicant did not provide the public with the best way of accomplishing the invention, but, instead, provided a recipe for growing cells which might be equivalent but also, "could be worse." [15]

III. THE DECISION BELOW VIOLATES FUNDAMENTAL PATENT PRINCIPLES BY SUBORDINATING THE PUBLIC INTEREST

The decision below contrasts sharply with this Court's recent statement that the public interest is "the ultimate goal" and "centerpiece" of our patent laws. This Court has recognized that "the ultimate goal of public disclosure and use . . . is the centerpiece of federal patent policy." [16] It is critically important that the Court address the issues raised by the lower court decision because that decision reflects a serious shift in how the patent system will be administered. It is not immediately apparent from reading the Federal Circuit's decision that the patent system is anything more than a handful of statutes without any particular vision.

The lower court reached that result by ignoring decisions of this Court and, astonishingly, its own earlier decisions, as well as those of its predecessor courts.[17] It is

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[15] Opinion below, at 1211.

[16] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989).

[17] In the absence of intercircuit conflicts, both the Court and potential *amici* now face an increased burden in identifying cases demanding Supreme Court attention. Despite increased attention in the literature to this problem, there is no clear test for cases that would have, in other circumstances, manifested themselves in intercircuit conflicts. While this *amicus* is not prepared to articulate such a general test, two instances clearly provide at least part of the functional equivalent for an intercircuit conflict: first,

therefore doubly important that this Court review the Federal Circuit's opinion here because, as wrong as that court got its science there, it has, with respect to the strong public interest in the patent system, repeatedly misconceived the nature of our patent laws. This Court, from its very first patent case,[18] to its most recent,[19] has ceaselessly and unabashedly recognized the patent grant as a monopoly. Nevertheless, the Federal Circuit has more than once denied the obvious, stating, "Nowhere in any statute is a patent described as a monopoly. . . . It is but an obfuscation to refer to a patent as 'the patent monopoly' or to describe a patent as an 'exception to the general rule against monopolies." [20] It is certainly inevitable that a court which refuses to recognize the essential monopoly nature of a patent will tend to give the public interest short shrift.

Viewed in context, then, it is unsurprising, though no less inappropriate, that the decision below continues to redefine patent concepts and contradict established case law. Until now, the Federal Circuit, as did its predecessor court before it, has repeatedly defined the "best mode" test as a subjective one going to the inventor's state of mind, and the "enablement" test as an objective one addressing the abilities of the hypothetical person skilled in the pertinent art.[21] The first asks whether the

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when Federal Circuit decisions conflict with Supreme Court cases; second, when Federal Circuit decisions appear to be in conflict with one another. In this case, both tests are satisfied.

[18] *Evans v. Eaton*, 16 U.S. 454, 519 (1818).

[19] *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989).

[20] *Carl Schenck, A.G. v. Norton Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

[21] *In re Bundy*, 642 F.2d 430 (C.C.P.A. 1981); *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940-942 (Fed. Cir. 1990); *Chemcast Corp. v. Arco Industries Corp.*, 913 F.2d 823, 926-928 (Fed. Cir. 1990).

inventor subjectively knew and concealed a better way to replicate the invention. The second asks whether others could reasonably replicate it. As a result, the possibility that reasonable experimentation—an objective test—may be necessary to replicate the invention, as long as the amount required is not "undue", has always applied to the enablement test, the measure of adequate disclosure.[22] On the other hand, an objective measure has never applied to the first, "best mode" inquiry into whether the inventor subjectively knew of a better mode. It should not matter, under all the precedents, if later inventors could, by experimentation, discover the inventor's secrets if the inventor knew, at the time of application, a better mode than what he made public. Here, however, the inventor physically possessed the best mode—the cells themselves—and kept it to itself.

Nevertheless, the Federal Circuit held that the "best mode" requirement was not violated because later experimenters had a possibility of replicating something similar to the inventor's cells, though admittedly the result "could be better, could be worse."[23] Never has a patent case held that because others might through experimentation rediscover the invention, an inventor could withhold the secrets of his discovery. The Federal Circuit, for the first time, has effectively combined the two tests, obliterating the subjective element by applying the "reasonable experimentation" test to it. The decision below effectively states that even if the inventor knew of a better mode, the best mode requirement is not violated as long as there are others who will be persistent and competent enough to discover something akin to it on their own. But to apply an objective standard to best mode—to allow the inventor to force others to experiment to discover an approximation of his secret—is to shortchange the public of its bargain.

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[22] *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 940-942 (1990).

[23] Opinion below, at 1211.

CONCLUSION

It must be reiterated, that were the merits of this particular case the sole issue, this *amicus* would not feel compelled to request review by the Supreme Court. The mistakes over the merits of this case, however, arise directly from a profound misconception about the nature of the patent system itself. If uncorrected, that misconception will slowly, but quite surely, erode the valuable merits of that statutory scheme. It will just as inevitably impose upon the public the trade protectionism from which our modern democratic patent system may historically derive but which, by embracing the public interest, it expressly rejects.

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